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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,847	12/09/2005	Richard Joseph Fagan	C&R-107	5016

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EXAMINER	
KAM, CHIH MIN	
ART UNIT	PAPER NUMBER
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,847	FAGAN ET AL.	
	Examiner	Art Unit	
	CHIH-MIN KAM	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *47-74* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. In the preliminary amendment filed June 25, 2005, claims 1-46 have been cancelled, and new claims 47-74 have been added. Therefore, claims 47-74 are pending.

2. Claims 54-72 are improper dependent claims because the claims are dependent from two separate claims, where the claim should refer to other claims in the alternative only.

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group 1, claims 47 a), i), j), 48, 49a), i), 54, 55, 62, 63 and 73-74, drawn to a composition of matter comprising an isolated polypeptide selected from the group of an amino acid sequence of SEQ ID NO:14, SEQ ID NO:34, SEQ ID NO:36 and functional fragment thereof; and a method of using the composition of matter in diagnosing a disease in a patient.

Group 2, claims 47 b), c), d), i), j), drawn to a composition of matter comprising a purified nucleic acid molecule, which encodes an amino acid sequence of SEQ ID NO:14, SEQ ID NO:34, SEQ ID NO:36 and functional fragment thereof; a vector comprising a nucleic acid sequence of SEQ ID NO:13, SEQ ID NO:33, SEQ ID NO:35 and fragment thereof; a vector comprising the nucleic acid molecule, SEQ ID NO:38 or SEQ ID NO:39; and a host cell transfored with the nucleic acid or vector.

Group 3, claims 47 e), i), drawn to a composition of matter comprising a ligand that specifically binds to a polypeptide of SEQ ID NO:14, SEQ ID NO:34, SEQ ID NO:36 and functional fragment thereof.

Group 4, claims 47 f), i), drawn to a composition of matter comprising a compound that increases or decreases the level of expression or activity of a polypeptide of SEQ ID NO:14, SEQ ID NO:34, SEQ ID NO:36 and functional fragment thereof.

Group 5, claims 47 g), i), drawn to a composition of matter comprising a compound that binds to a polypeptide of SEQ ID NO:14, SEQ ID NO:34, SEQ ID NO:36 and functional fragment thereof without inducing any of the biological effects of the polypeptide.

Group 6, claims 47 h), i), drawn to a composition of matter comprising a compound that binds to a polypeptide of SEQ ID NO:14, SEQ ID NO:34, SEQ ID NO:36 and functional fragment thereof without inducing any of the biological effects of the polypeptide, where the compound is a natural or modified substrate, ligand, enzyme, receptor or structural or functional mimetic.

Group 7, claims 47 k), drawn to a kit for diagnosing disease, comprising a first container containing a nucleic acid probe that hybridizes under stringent conditions with a nucleic acid molecule of any one of b1) to b4), a second container containing primers useful for amplifying the nucleic acid molecule, and instructions for using the probe and primers for facilitating the diagnosis of disease.

Group 8, claims 47 l), drawn to a kit for diagnosing disease, comprising a first container containing a nucleic acid probe that hybridizes under stringent conditions with a nucleic acid molecule of any one of b1) to b4); a second container containing primers useful for amplifying

the nucleic acid molecule; a third container holding an agent for digesting unhybridized RNA; and instructions for using the probe and primers for facilitating the diagnosis of disease.

Group 9, claims 47 m), drawn to a kit comprising an array of nucleic acid molecules, at least one of which is a nucleic acid molecule according to any one of bl) to b4).

Group 10, claims 47 n), drawn to a kit comprising one or more antibodies that bind to a polypeptide as recited in any one of al) to a9); and a reagent useful for the detection of a binding reaction between the one or more antibodies and the polypeptide.

Group 11, claims 47 o), drawn to a transgenic or knockout non-human animal that has been transformed to express higher, lower, or absent levels of a polypeptide according to any one of al) to a9).

Group 12, claims 48, 49 a), i), 50-53 and 64-66, drawn to a method of treaing a disease in a patient, or monitoring the therapeutic treatment of a disease using the composition of matter comprising a polypeptide of 47 a).

Group 13, claims 48, 49 a) and 67-69, drawn to a method of identifying a compound that is effective in the treatment and/or diagnosis of a disease using the composition of matter comprising a polypeptide of 47 a).

Group 14, claims 48, 49 b), c), d), i), 54, 55 and 57-63, drawn to a method of diagnosing a disease in a patient using the composition of matter comprising a nucleic acid molecule or vector of 47 b), c).

Group 15, claims 48, 49 b), c), d), i), j), 50-53 and 64-66, drawn to a method of treating a disease in a patient, or monitoring the therapeutic treatment of a disease using the composition of matter comprising a nucleic acid molecule of 47 b), c).

Group 16, claims 48, 49 b), c), d), and 67-69, drawn to a method of identifying a compound that is effective in the treatment and/or diagnosis of a dicase using the composition of matter comprising a nucleic acid molecule of 47 b), c).

Group 17, claims 48, 49 e), i), 50-53 and 56, drawn to a method of treating a disease in a patient using the composition of matter comprising a ligand of 47 e).

Group 18, claims 48, 49 f), i), and 50-53, drawn to a method of treating a disease in a patient, or monitoring the therapeutic treatment of a disease using the composition of matter comprising a compound of 47 f).

Group 19, claims 48, 49 g), i) and 50-53, drawn to a method of treating a disease in a patient using the composition of matter comprising a compound of 47 g).

Group 20, claims 48, 49 h), i) and 50-53, drawn to a method of treating a disease in a patient using the composition of matter comprising a compound of 47 h).

Group 21, claims 48 and 70-72, drawn to a method of screening candidate compounds by contactinga non-human transgenic animal with a candidate compound and determining the effect of the compound on the disease of animal.

The claims of Groups 1-21 are directed to different inventions, which are not linked to form a single general concept. The claims in the different groups do not have in common the same or corresponding technical features. In particular, each group is directed to distinct

chemical entities and/or methods which use different materials and produce different effects. Accordingly, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept and lack of unity is deemed proper.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically

point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Species Election

This application contains claims directed to the following patentably distinct species of polypeptides (i.e., SEQ ID NOs: 14, 34 and 36 in claims 47 a) and 49 a)). The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species [a single amino acid sequence in claims 47 a) and 49 a)] from an elected group for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 47 or 49 is generic.

In addition, this application contains claims directed to the following patentably distinct species of polynucleotide sequences [i.e., SEQ ID NOs: 13, 33, 35, 38 and 39 in claims 47 b) and 49 b)]. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (one nucleotide sequence and the corresponding amino acid sequence] from an elected group for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 47 or 49 is generic.

Additionally, this application contains claims directed to the following patentably distinct species of diseases [i.e., diseases listed in claims 50, 51, 62, 63, 65, 66, 68, 69, 71 and 72]. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (one disease) from an elected group for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 48 or 54 is generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another

species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/
Primary Examiner, Art Unit 1656

CMK
March 1, 2008